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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,109	02/11/2004	Mohammad A. Kheiri	MSE #2666	2820

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NIXON PEABODY LLP
161 N. CLARK STREET
48TH FLOOR
CHICAGO, IL 60601

EXAMINER	
TANNER, JOCELIN C	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,109	KHEIRI, MOHAMMAD A.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed 3 October 2008. Claims 1-21 are currently pending. The Examiner acknowledges the amendments to claim 6 and 11 and the cancellation of claim 17.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 4, 5, 11,12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison (WO 01/62150 A1).**

3. Regarding claim **1**, Davison discloses a skin pricker or “lancing device" including a housing or “body”, a platform or “contact face” (2) with both inner and outer portions, an aperture or “opening” (3) in the inner portion of the contact face and a contact face having “pressure points” shaped as serrations or “ribs” (4) with channels separating each rib. Davison discloses a pattern wherein the ribs, that are elongated teeth arranged like spokes of a wheel, are arranged around the contact face and extend from the inner and outer portions (column 1, lines 24-27, Fig. 1).

4. Regarding claims **4**, Davison discloses concentric ribbed pressure points (4) arranged around the opening (column 1, lines 23-24, Fig. 1, element #3).

5. Regarding claims **5**, Davison discloses pressure points (4) that radially extend from the opening to the circumference of the contact face in an annular array (column 1, lines 26-27).

6. Regarding claims **11 and 12**, Davison discloses a method of drawing a sample including the steps:

providing a lancing device having a nose cap or "endcap" (1), an annular platform or contact face" (2) with both inner and outer portions, a contact face having "pressure points" shaped as serrations, i.e. elongated teeth or spokes, or "ribs" (4) extending radially from the opening (3) to the circumference of the contact face (column 1, lines 24-27, Fig. 1).

placing the contact face (2) onto the site (column 1, lines 19-21, column 2, lines 1-6);

actuating and exposing the lancet through the opening (column 2, lines 13-14);

massaging or pressing the site with the contact face (2) to cause blood to flow to puncture (column 2, lines 19-20).

7. Regarding claim **16**, Davison discloses massaging the sample site through the application of constant pressure (column 2, lines 19-20).

8. **Claims 1, 4, 11, 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Verdonk et al. (6,306,152).**

9. Regarding claim **1**, Verdonk et al. discloses an endcap having a barrel or "body" (202), a contact face with both inner and outer portions, a central bore or "opening"

(204) in the inner portion of the contact face wherein a plurality of legs or "pressure points" that are shaped as "ribs" (200) with channels separating each rib, encircle the opening and extend from the inner and outer portions (column 5, lines 24-27, Fig. 9).

10. Regarding claim **4**, Verdonk et al. discloses concentric ribbed pressure points (200) arranged around the opening (Fig. 9).

11. Regarding claims **5**, Verdonk et al. discloses pressure points (200) that radially extend from the opening to the circumference of the contact face in an annular array (Fig. 9).

12. Regarding claims **11 and 12**, Verdonk et al. discloses a method of drawing a sample including the steps:

providing a lancing device having an endcap, a contact face with both inner and outer portions, a contact face having a plurality of legs or "ribs" (200) that are arranged in a ring-like pattern extending radially from the central bore or "opening" (204) to the circumference of the contact face (column 5, lines 24-27, Fig. 9).

placing the contact face onto the site (column 5, lines 23-24);

actuating and exposing the lancet through the opening (column 5, lines 43-52);

massaging or pressing the site with the contact face to cause blood to flow to puncture (column 5, lines 47-48).

13. Regarding claim **16**, Verdonk et al. discloses massaging the sample site through the application of constant pressure (column 5, lines 19-20).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **Claims 2, 3, 6-10, 18-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Davison (WO 01/62150 A1) in view of Moerman (US Patent No. 6,706,049).**

16. Regarding claims **2 and 8,** Davison fails to disclose the body of the endcap being made of transparent material.

Moerman teaches a cap for use with a lancing device wherein the cap body or "body" (81) is constructed from transparent or clear material (column 8, lines 46-51, FIG. 10).

Since, Davison and Moerman teach known devices, i.e. endcaps for lancing devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the body of Davison with the transparent material, as taught by Moerman, for the predictable result of viewing and monitoring the expressed blood at a lancing site.

17. Regarding claims **3** and **6**, Davison discloses a contact face (2), an aperture (3) within the contact face for the projection of a lancet, and a pattern of ribs arranged in an annular array around the aperture wherein channels are defined as the spaces between

the ribs (column 1, lines13-14, lines 26-27). However, Davison fails to disclose a concave contact face.

Moerman teaches a contact ring or "contact face" (85) connected to the cap body (81) of a lancing device wherein the contact face has non-planar surfaces disposed at distinct angles relative to each forming a concave interior (column 5, lines 41-45, column 9, lines 1-3, Fig. 10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the contact face of Davison with the concave face, as taught by Moerman, to facilitate and maximize blood expression by creating a pressure gradient that extends radially inwardly towards the opening.

18. Regarding claim **7**, Davison discloses a rib pattern of serrations or "ribs" (4) wherein a groove or channel separates each rib (column 1, lines 26-27).

19. Regarding claim **9**, Davison discloses concentric ribbed pressure points (4) arranged around the opening (column 1, lines 23-24, Fig. 1, element #3).

20. Regarding claim **10**, Davison discloses pressure points (4) that radially extend from the opening to the circumference of the contact face in an annular array (column 1, lines 26-27).

21. Regarding claim **18,** Moerman teaches the method of beveling or forming an incline toward the aperture of a contact face (85) wherein gradual reduction of pressure is provided as the contact face is applied to the site (column 9, lines 1-3, column 9, lines 25-27,Fig. 10).

22. Regarding claim **19,** Moerman teaches the viewing of expressed blood through a transparent endcap (column 8, lines 46-51, Fig. 10, element #81).

23. Regarding claim **20,** Moerman teaches expressing a fluid sample of blood using a lancet (column 4,lines 56-57).

24. Regarding claim **21,** Moerman teaches the collecting of samples from alternate lancing sites including forearms, upper arms and thighs (column 4, lines 1-5).

25. **Claims 2, 3, 6- 10, 18-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Verdonk et al. (6,306,152) in view of Moerman (US Patent No. 6,706,049).**

26. Regarding claims **2 and 8,** Davison fails to disclose the body of the endcap being made of transparent material.

Moerman teaches a cap for use with a lancing device wherein the cap body or "body" (81) is constructed from transparent or clear material (column 8, lines 46-51, FIG. 10).

Since, Verdonk et al. and Moerman teach known devices, i.e. endcaps for lancing devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the body of Verdonk et al. with the transparent material, as taught by Moerman, for the predictable result of viewing and monitoring the expressed blood at a lancing site.

27. Regarding claims **3** and **6**, Verdonk et al. discloses a contact face, a central bore or “aperture” (204) within the contact face for the projection of a lancet, and a pattern of ribs arranged in an annular array around the aperture wherein channels are defined as

spaces between the ribs (column 5, lines 25-31, Fig. 9). However, Verdonk et al. fails to disclose a concave contact face.

Moerman teaches a contact ring or "contact face" (85) connected to the cap body (81) of a lancing device wherein the contact face has non-planar surfaces disposed at distinct angles relative to each forming a concave interior (column 5, lines 41-45, column 9, lines 1-3, Fig. 10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the contact face of Verdonk et al. with the concave face, as taught by Moerman, to facilitate and maximize blood expression by creating a pressure gradient that extends radially inwardly towards the opening.

28. Regarding claim **7**, Verdonk et al. discloses a rib pattern of legs or "ribs" (200) wherein a groove or channel sepaates each rib (Fig. 9).

29. Regarding claim **9**, Verdonk et al. discloses concentric ribbed pressure points (200) arranged around the opening (Fig. 9).

30. Regarding claim **10**, Verdonk et al. discloses pressure points (200) that radially extend from the opening to the circumference of the contact face in an annular array (Fig. 9).

31. Regarding claim **18,** Moerman teaches the method of beveling or forming an incline toward the aperture of a contact face (85) wherein gradual reduction of pressure is provided as the contact face is applied to the site (column 9, lines 1-3, column 9, lines 25-27,Fig. 10).

32. Regarding claim **19,** Moerman teaches the viewing of expressed blood through a transparent endcap (column 8, lines 46-51, Fig. 10, element #81).

33. Regarding claim **20,** Moerman teaches expressing a fluid sample of blood using a lancet (column 4,lines 56-57).

34. Regarding claim **21,** Moerman teaches the collecting of samples from alternate lancing sites including forearms, upper arms and thighs (column 4, lines 1-5).

35. **Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davison (WO 01/62150 A1) in view of Douglas et al. (US Patent No. 6,332,871).**

36. Regarding claims **13-15,** Davison fails to teach the method of alternating turns, rocking and back and forth movements as forms of massaging a lancing site.

Douglas et al. teach a sampling device and the use of massage patterns to increase momentary blood flow such as rubbing, which involves moving back and forth or rocking, and a squeegee motion that incorporates a turning motion.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the massaging techniques with the endcap of Davison, as taught by Douglas et al., to stimulate the capillaries and enhance the flow of blood in the alternative lancing regions.

37. **Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verdonk et al. (6,306,152) in view of Douglas et al. (US Patent No. 6,332,871).**

38. Regarding claims **13-15,** Verdonk et al. fails to teach the method of alternating turns, rocking and back and forth movements as forms of massaging a lancing site.

Douglas et al. teach a sampling device and the use of massage patterns to increase momentary blood flow such as rubbing, which involves moving back and forth or rocking, and a squeegee motion that incorporates a turning motion.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the massaging techniques with the endcap of Verdonk et al., as taught by Douglas et al., to stimulate the capillaries and enhance the flow of blood in the alternative lancing regions.

Response to Arguments

1. Applicant's arguments filed 3 October 2008 have been fully considered but they are not persuasive. The Applicant contends that Davison does not disclose a plurality of ribs with channels defined between adjacent ribs, however Davison discloses elongate teeth or serrations, a row of notches which would define channels between adjacent notches. The Applicant contends that Davison does not disclose the ribs extending from the outer portion of the contact face toward the inner portion. However, Davison discloses elongate teeth or "ribs" that are located in exterior area or "portion" that is not adjacent to the aperture and extend to the area immediately surrounding the aperture. Davison further discloses that the number, arrangement, size and shape may differ. Furthermore, spacing or “channels” must be defined between each separate cone stud or “rib” in order to have separate studs.

2. The Applicant contends that Verdonk fails to disclose a plurality of ribs with channels defined between the adjacent ribs, however, figure 9 shows several ribs that are separated by channels. The Applicant contends that Verdonk fails to disclose inner

and outer portions of the contact face, however, Verdonk discloses an inner portion that is adjacent to the aperture and an outer portion that is near the edge of the contact face. The Applicant contends that stressing and straining of the skin tissue is far different from "massaging", however, stressing and straining is stretching and pulling of the skin which would be a type of massaging when repeatedly performed.

3. The Applicant contends that there is no motivation to combine the radially inwardly extending pressure-gradient of Moerman with Davison since Moerman only includes a depression and does not include any projections or ribs. However, Moerman teaches multi-contoured surface that can be formed to have selected surface features including protrusions or indentions (column 6, lines 31-37).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
4/20/2009
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/22/09